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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/966,768      | 09/28/2001  | Derek Van Der Kooy   | Bereskin & Parr     | 6817             |

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DANN, DORFMAN, HERRELL & SKILLMAN

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PHILADELPHIA, PA 19103-2307

EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                     |  |
|------------------------------|-------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/966,768 | Applicant(s)<br>VAN DER KOOY ET AL. |  |
|                              | Examiner<br>Daniel M Sullivan | Art Unit<br>1636                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004 and 18 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13-17, 20-22, 25-38, 41-43 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 13-17, 20-22, 25-27, 29-38, 41, 42 and 47-49 is/are allowed.
- 6) ☒ Claim(s) 28 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This Office Action is a response to the Papers filed 23 February 2004 and 18 June 2004 in reply to the Non-Final Office Action mailed 20 November 2003. Claims 1-11, 13-17, 20-22, 25-38, 40-43 and 47-49 were considered in the 20 November Office Action. Claims 28, 33, 35, 36 and 41-43 were amended and claim 40 was canceled in the 23 February Paper. Claims 1-11, 13-17, 20-22, 25-38, 41-43 and 47-49 are pending and under consideration.

### ***Response to Amendment***

#### Claim Objections

Objection to claim 28 is withdrawn.

#### Claim Rejections - 35 USC § 112

Rejection of claims 35 and 36 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed invention is withdrawn.

Rejection of claims 33-36 and 40-43 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Claim 28 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons of record.

The claim was rejected on the grounds that it recites an intended use for the claimed method that is distinct from the intended use of the method from which it

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depends but fails to set forth any method steps that would accomplish the intended use. In response, Applicant has amended the claims such that it now directed to the method of claim 1 further comprising analyzing the role of genes in the regulation of neural fate specification. The method is described on page 6 of the specification. With regard to specific process steps, the teachings found there provides only, "[i]n one embodiment this can be done by detecting the presence or absence of gene expression through convention [sic] techniques such as RT-PCR or methods of protein expression analysis." However, it is unclear from these teachings how "the role of genes in the regulation of neural fate specification" is determined by this procedure. It would seem that the method steps described would merely establish a coincidental change in gene expression rather than an actual role for a gene in neural cell fate specification. Therefore, it would appear that critical method steps are missing.

***New Grounds Necessitated by Amendment***

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06).

The MPEP further states, “[w]henver the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, claim 43 has been amended to recite that the method comprises the step of culturing the cells of claim 1 in transplantation media. The originally filed disclosure contains no description of “transplantation media” and no recitation of culturing cells in a transplantation media. Thus, there is no support for a method comprising culturing cells in transplantation media in the originally filed specification and claims. Therefore, the limitation constitutes new matter and the claim is rejected under 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in the recitation of “transplantation media”. As the specification contains no definition of transplantation media (*Id.*) it is unclear what distinguishes transplantation media from other media. Thus, the metes and bounds of the claim are unclear.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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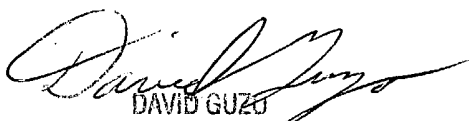
advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER